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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/689,730	10/13/2000	Motoharu Seiki	0055-0310P	6821

2292 7590 12/03/2002

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EXAMINER
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PROUTY, REBECCA E

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 12/03/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.  
09/689,730

Applicant(s)  
Seiki et al.

Examiner  
Rebecca Prouty

Art Unit  
1652



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Oct 9, 2002

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 13-22 is/are pending in the application.

4a) Of the above, claim(s) 16, 17, 21, and 22 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 13, 15, 18, and 20 is/are rejected.

7)  Claim(s) 14 and 19 is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some\* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. 08/448,889.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_\_

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Claims 1-12 have been canceled. Claims 13-22 are at issue and are present for examination.

Applicant's election of Group I, Claims 13-15 and 18-20 in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 16-17 and 21-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 9.

The amendment filed 10-13-00 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the amendments to pages 1, 2 and 8 to insert "polyclonal" antibodies. Applicants argument that this is not new matter as Example 3(c) produces polyclonal antibodies and the hybridoma of Example 3(e) produces polyclonal antibodies is noted. However, Example 3(c) is presented is merely one step in the process of producing the monoclonal antibodies that are part of the original disclosed invention. The hybridoma of Example 3(e) does not produce

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polyclonal antibodies but a monoclonal antibody. As such the original disclosure does not in any way suggest that polyclonal antibodies were considered part of applicants invention at the time of filing.

Applicant is required to cancel the new matter in the reply to this Office Action.

Applicant is advised that should claims 13-15 be found allowable, claims 18-20 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). While the wording of Claims 13 and 18 is different (with 13 including a lot of unnecessary language describing the protein encoded by the claimed DNA), both claims are limited to a DNA having the sequence shown in SEQ ID NO:2. As such the claims are duplicative. Claims 14 and 19 are similarly limited to a plasmid comprising a DNA having the sequence shown in SEQ ID NO:2 and Claims 15 and 20 are similarly limited to a host cell transformed with a plasmid comprising a DNA having the sequence shown in SEQ ID NO:2. As such claims 14 and 19 are duplicative and claims 15 and 20 are duplicative.

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35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 13 and 18 are rejected under 35 U.S.C. § 101 because the claimed invention is directed toward non-statutory subject matter. In the absence of the hand of man, naturally occurring DNAs are considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). This rejection may be overcome by amending the claims to contain wording such as "An isolated DNA ..." .

Claims 15 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15 and 20 are confusing in the recitation of "host cell harboring a plasmid" as this is non-standard terminology in the art and is not defined within the specification. Is this intended to mean "transformed with".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Rebecca Prouty  
Primary Examiner  
Art Unit 1652